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June 16, 2000

VIA TELEFAX AND OVERNIGHT COURIER

Patricia Hick, Esq.
Assistant Regional Counsel, Office of Regional Counsel
U.S. Environmental Protection Agency - Region 2
290 Broadway, 19th Floor - Room W-20
New York, NY 10007-1866

Re: Creel/Angler Survey
Remedial Investigation/Feasibility Study for the
Passaic River Study Area, Index No. II - CERCLA - 0117
April 27, 2000 Letter and May 23, 2000 Meeting

Dear Ms. Hick:

Thank you for the opportunity to meet on May 23, 2000, to discuss EPA's letter of April 27, 2000, from Sharon Jaffess to Cliff Firstenberg. On behalf of our client, Chemical Land Holdings, Inc. (CLH) (acting on behalf of Occidental Chemical Corporation), by this letter we respond both to EPA's April 27, 2000, letter and to matters addressed in our meeting. CLH submitted under separate cover letter from Cliff Firstenberg to Sharon Jaffess dated May 26, 2000, printouts of CLH's slides presented at the meeting, a copy of the agenda and attendee list, and a memorandum of meeting notes.

We reviewed during our meeting the long history of the Creel/Angler Survey which has been an integral component of the Ecological Sampling Plan (ESP) since 1995. With this letter we again review the background and history of the Creel/Angler Survey, discuss our view of the import of EPA's decision to forego the Survey as stated in the referenced letter and discussed in our May 23 meeting, and respectfully request that EPA reconsider this decision.

Background

CLH has worked cooperatively for many years with EPA and NJDEP to investigate conditions in the Passaic River. After lengthy, complicated negotiations during 1993-94, CLH agreed to enter into the Administrative Order on Consent (AOC) and to perform the work required ultimately to result in preparation of the Remedial Investigation/Feasibility Study (RI/FS) for the Passaic River Study Area.

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An extremely difficult hurdle for CLH in its internal deliberations about whether ultimately to execute the AOC concerned EPA's demand that the AOC include a provision for conduct of the ESP. CLH's reluctance about the ESP stemmed from the Company's deep-rooted concern that implementing an ESP would be extremely costly and that the likelihood of obtaining useful data was not commensurate with the cost of collecting and analyzing such data. However, because the AOC provided that CLH could, under the AOC, decline to conduct the ESP, and because the AOC and Scope of Work (SOW) contained standards of performance, such as collection of local, site-specific data on fishing and consumption, CLH executed the AOC.

Following its review of the Screening Level Human and Ecological Risk Assessment (HERA), by letter dated October 27, 1995 (R. Basso to M. Skaggs), EPA directed CLH to prepare the draft ESP and further directed CLH to use EPA's attached SOW framework to prepare the draft ESP. The portion of the SOW relevant to the issue at hand (see Section IV of the Attachment to EPA's October 27, 1995 letter) is quoted below:

IV. Fish Consumption/Creel Survey

Objectives/Rationale

It is not reasonable to assume that "the potentially exposed population for the Site resembles the angling population surveyed by Belton et al. (1985)." The Passaic River Study Area has limited fishing access and therefore most likely attracts a different fishing population. Additionally, the local populations surveyed in Belton are not comparable to the ethnic make-up of the local populations in the Study Area. Finally, ten years can make a significant difference in fishing population makeup in a highly urban area which may see substantial and rapid population turnovers.

Approach

An in depth fish consumption/creel survey spanning several seasons should be conducted. Personnel conducting the interviews should be knowledgeable in interview techniques which have proven success in this general location. Interpreters conversant in English, Portuguese and Spanish will be necessary. A detailed, site-specific consumable biota tissue analysis must be incorporated in the study as well.

The inclusion of this Fish Consumption/Creel Survey (hereinafter Creel/Angler Survey) was a material inducement by EPA to CLH's decision to agree to implement the ESP. CLH believed it could rely on EPA's conclusion with respect to the ESP including the Creel/Angler Survey. CLH

believed (and continues to believe) that it would improve the reliability of the HERA and thus justify the considerable cost to implement the ESP.

History

Until April 27, 2000, for five years EPA has clearly and consistently directed CLH to collect site-specific data for the conduct of the HERA. EPA has characterized the data to be gathered in the Creel/Angler Survey as an integral part of the data required for an "appropriate, defensible assessment of the risk to human health and the environment in the Passaic River Study Area." (Letter L. Richman to S. Burton, December 12, 1995).

In the above-referenced October 27, 1995, letter, EPA stated its determination that "additional information is required to complete the Human and Ecological Risk Assessment." The language earlier quoted from the attachment to EPA's October 1995 letter makes clear that site-specific information on the exposed population for the Passaic River Study Area is needed because: (1) the River has limited fishing access; (2) substantial, rapid population turnover may affect ethnic makeup of the local population, presumably affecting fish consumption practices; and (3) existing surveys in the literature would not be representative. The attachment to EPA's December 12, 1995 letter provides draft comments on the Screening Level HERA that further describe EPA's view that "sufficient data is [sic] not currently available to conduct a sound risk assessment" for the Passaic River Study Area. EPA stated that any revisions to the Screening Level HERA would be premature, absent additional data, and the attached comments are replete with explication of data needed on fishing and consumption habits for the Study Area.¹

Identification of populations of concern is a significant data gap discussed in EPA's December 12, 1995 attachment, the failure of which to evaluate EPA said would result in a "potential underestimation of the fish consumption," including that of the Portuguese community, which EPA postulated may have higher fish consumption rates than the general population. Additionally, that the mean household income in the Study Area is less than the state average "can increase the probability of community members fishing the waters to supplement food sources" (at page 2). The comments at page 4 raised other fish consumption questions. At page 5, the comments further detail concerns about subpopulations and the potential to underestimate risks, and at page 6, additional comment is provided regarding the potential for ethnic-specific cooking practices and degree of mobility in the community. Page 6 notes that the existing data will not support a Monte Carlo analysis. EPA's conclusion to this portion of its comments is absolutely clear about the necessity to sample fish populations, sediment, and fish consumption rates: "[A]dequate data is [sic]

¹These attached comments appear to have been written earlier in contemplation of or preparatory to EPA's October 1995 directive that CLH prepare the ESP.

not available to conduct a risk assessment at this time and this sampling is crucial to providing this information for a risk assessment.” EPA does not say that inadequate data exist and need be collected only for fish and sediment, but rather that sampling is crucial to provide adequate data for all three issues -- sediment, fish tissue and fish consumption -- for use in preparing the HERA.

EPA after making this clear statement provides specific comments about fish consumption, especially for subsistence anglers (page 13), such as that the potential exists for socioeconomics to result in assumptions that underestimate the fishing population because of lack of access to transportation to fish (page 14), and that economic concerns might outweigh the fishing prohibition. In discussing detailed exposure parameters at page 16,² the comments express the view that Site population characteristics “should be replaced with a *[sic]* detailed fish consumption survey data.” This is reinforced on page 17. “[A] detailed site-specific consumption survey to obtain consumption rates for key species, both average and RME, is required.”

EPA’s expression of need for site-specific angler survey data continues in its April 15, 1996 letter (R. Basso to M. Skaggs), which required revisions to the ESP as specified in attached comments that set forth site-specific Study Area issues. The required revisions to the Creel/Angler Survey were discussed in a conference call between EPA and CLH as memorialized in a letter dated May 31, 1996 (S. Burton to L. Richman). There was agreement that “comments are topics that would be addressed in a Creel/Angler Survey Work Plan.” Further, “[T]he on-site survey is planned to be the sole source of information used to quantify fish and shellfish consumption rates and to identify any subsistence angling populations using the Passaic River within the Study Area.” This letter concludes with a statement of Maxus’ (now CLH’s) understanding that it would revise the Creel/Angler Survey section of the draft ESP to “provide additional detail about the plans for designing, conducting, and analyzing data” from the Creel/Angler Survey³ in the form of a description of the Creel/Angler Survey Work Plan.⁴

²The comments say to conduct a “detailed consumable biota tissue analysis” or use Belton (1985) estimated consumption frequencies. The Belton study was published 15 years ago and does not contain data collected from any portion of the Passaic River. Use of the Belton Study would directly contravene EPA’s directives and guidance to use site-specific, current data.

³CLH has removed the household survey from the revised draft Creel/Angler Survey Work Plan in consideration of written informal comments by EPA and discussions at our May 23, 2000, meeting. No further references to the household survey will be included in this letter.

⁴The Work Plan will include the formal Scope of Work for the survey, the survey instruments, and plans for management and analysis of the survey data.

Two years ago the parties met on May 4, 1998, and the meeting agenda included discussion of the Creel/Angler Survey being required in the ESP because there is "No site-specific fish consumption data," because "default consumption rates [are] not appropriate for Study Area," and because the "HERA cannot be completed without a Creel/Angler Survey," notwithstanding that by this time EPA's published default consumption numbers had been available for nearly a year, and presumably, officials also were aware of the pending publication prior to the August 1997 release of the *Exposure Factors Handbook*. Visual aids for this meeting show it addressed why default consumption rates were not representative and why the "Creel/Angler Survey is an essential part" of the ESP. This is further memorialized in the summary of the meeting (Letter to P. Evangelista from A. Pittignano dated May 11, 1998), which states the conclusion that "EPA agreed that the Creel/Angler Survey should be included in the ESP and that the Creel/Angler Survey Work Plan should be submitted in accordance with the schedule included in [the] last version of the ESP." This was confirmed in Sharon Jaffess' letter of November 9, 1998, to A. Pittignano. Thereafter, on March 17, 1999, in a meeting between Ms. Jaffess and Mr. Pittignano, it was agreed that the Creel/Angler Survey portion of the ESP would remain in the body of the document, rather than be removed to the appendices, and that there would be a meeting in April of 1999 to discuss the minimum requirements for the Creel/Angler Study.

EPA never scheduled such a meeting. However, by letter of April 6, 1999 (Jaffess to Pittignano), the Agency approved the ESP submitted by CLH. EPA specifically requested that CLH give up part of the 45 days provided in the AOC for CLH to decide whether it would implement the ESP. Giving up more than two weeks of its 45 days, CLH agreed by letter of May 3, 1999 (Skaggs to Jaffess), to perform the ESP "as approved by EPA and as otherwise provided in the Statement of Work, Appendix 1" to the AOC. Please note that CLH agreed to implement the ESP as approved by EPA (that is, with it including the Creel/Angler Survey). CLH did not agree to implement the approved ESP with any expectation that this ESP subsequently could arbitrarily modified by EPA to forego data collection in order to make up time lost as a result of Agency delay. CLH in good faith timely prepared the Creel/Angler Survey Work Plan for the ESP and submitted it by letter of June 29, 1999 (Pittignano to Jaffess), having a week earlier by electronic mail advised EPA that it was about to submit this Work Plan, and inquiring how many copies EPA wanted. EPA's response expressed desire to meet about schedules.

EPA finally sent informal technical comments electronically (Jaffess to Firstenberg) on January 27, 2000. A letter the next day (January 28, 2000, Jaffess to Firstenberg) confirmed this transmittal and set forth schedule dates, including July 31, 2001, for submittal of the Creel/Angler Survey data analysis. There was no further exchange of correspondence, only requests from CLH that EPA approve the Creel/Angler Survey Work Plan. EPA's delay in approving the plan became so grave, in our view, that finally, on February 18, 2000, I called Kedari Reddy of your office while you were on leave, urging that EPA formally provide CLH its comments. Later at my request, I met with Delmar Karlen and Ms. Reddy on March 21, 2000, to review the history of EPA's extremely

lengthy delays in responding on various items during the conduct of the RI/FS. At that meeting I showed Mr. Karlen and Ms. Reddy a timeline (a copy of which is enclosed herewith) to illustrate the impact of EPA's delays on the schedule and the ultimate completion date of the RI/FS and urged that the Agency complete its review of the Creel/Angler Survey Work Plan so CLH could commence the Survey. Some five weeks after this meeting and ten months after submittal of the draft Work Plan, EPA advised CLH that conducting the Creel/Angler Survey would take too long and eliminated it from the overall study plan.

On behalf of CLH, we object to EPA's abrupt, unsupported and, we believe, unsupportable, reversal of a consistent position nearly five years after directing CLH as part of the ESP to conduct the Creel/Angler Survey in order to collect site-specific data for the preparation of the Risk Assessment and CLH having agreed to undertake and having already implemented the ESP in reliance upon EPA's directive.

EPA Guidance

In our view, which is based upon EPA guidance and review of studies of fishing practices in the Newark Bay region, site-specific Creel/Angler Survey data are absolutely essential for the HERA.

EPA's risk assessment guidance for years has plainly and consistently recognized the reality of wide variability in fish consumption and the need for site-specific surveys. For example, in its 1989 *Guidance Manual, Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish*, EPA recommends that "local or regional assessments of fishing consumption be performed whenever possible to amend possible errors inherent in extrapolating standard values for the U.S. population to distinct subpopulations" (page 54). In the preamble to its 1992 *Guidelines for Exposure Assessment*, EPA cautions that "obviously general default values should not be used in place of known, valid data that are more relevant to the assessment being done" (57 Fed. Reg. at 22914). In its November 1998 *Guidance for Conducting Fish and Wildlife Consumption Surveys*, at page 2-8 EPA reiterates its 1992 conclusion from *Consumption Surveys for Fish and Shellfish: A Review and Analysis of Survey Methods* that "fish consumption rates can vary widely in the human population," citing several studies that "have noted that a single point estimate is inadequate to represent consumption rates for a population because of the inherent variability in the consuming populations . . ."

In this same 1998 guidance, EPA also reiterates the conclusion found in its 1992 guidance that "consumption rates 'will have a significant impact on the risk estimations and on the selection of fish consumption limits'. . ." At page 3-1 of the 1998 guidance, EPA opines that "most states do not have sufficient data available to calculate local consumption rates or to identify special populations at risk." Accordingly, it notes that the need for more site-specific fish "... consumption

surveys has become more apparent.” At page 88 of its July 1998 *Ambient Water Quality Criteria Derivation Methodology Human Health*, EPA states that “Generally, the more specific the data are to the individuals who use the water body of interest, the better the data are considered to be for estimating accurate fish intake rates.”

Clearly, as these examples demonstrate, it is EPA’s longstanding position that site-specific data are preferable to default values in risk assessment. Indeed, the above-referenced publication of guidance on collecting such data for the specific case of fish consumption after the release of the *Exposure Factors Handbook* in 1997 demonstrates EPA’s recognition that the default rates in the *Exposure Factors Handbook* are not the final word on representative fish consumption rates. Moreover, neither the default fish consumption rates nor the studies upon which they were based provide information that will allow EPA and CLH to accurately assess site-specific exposures to children, nursing infants, pregnant mothers, subsistence populations, or other subpopulations who may be exposed to chemicals in fish or crab at the Passaic River Study Area.

Public Studies in the Newark Bay Area

While of interest for characterizing awareness of and response to fishing advisories and for providing consumption rates, the published information from studies conducted in the Newark Bay area is unfortunately not suitable for representative quantitative risk assessment for the Passaic River Study Area. The studies published in 1999 by Burger *et al.* and Kirk Pflugh *et al.* present conclusions from a summer 1995 study that focused on awareness of advisories; they do not present consumption rates or other quantitative information necessary for risk assessment. The study published by May and Burger in 1996 resulted from a summer 1994 study conducted at the Arthur Kill, Raritan Bay, and the New Jersey Atlantic Shore. While this study collected consumption information from an area near the Passaic River Study Area, the published information cannot support an accurate risk assessment because the study did not rely on measurement of creel catch or recall of consumption within a defined period, did not assess the relationship between seasons and species availability or between seasons and consumption behavior, and did not consider the relationship between age and fishing behavior. These shortcomings render it unacceptable for use in support of a comprehensive human health risk assessment for the Passaic River Study Area.

EPA’s Reversal of Long-Standing Position

In it April 27, 2000, letter EPA cited the existence of a “. . . long-standing. . . advisory against consumption of fish and other marine creatures. . .” and the biases and uncertainties that would “necessarily” be introduced due to its existence. During our meeting on May 23, 2000, CLH demonstrated to EPA, through a 1-hour presentation by expert consultants in risk assessment and creel/angler surveys, that there was no basis for EPA’s claim of a suppression effect causing bias to the data to be collected during the Survey. In fact, CLH demonstrated that the studies conducted by

EPA's own allied expert (Dr. Kirk Pflugh, NJDEP) could not identify any suppression effect, and numerous studies cited by EPA reported little or no effect due to advisories (any qualified effect was shown to be very much smaller than other uncertainties in the process, and far less than the uncertainties inherent in using default values in lieu of site-specific data). After EPA's caucus to discuss the information presented by the CLH team, EPA acknowledged that indeed, a valid, defensible creel/angler survey could be performed.

Frankly, we are surprised and dismayed by EPA's change of position. The Agency's unwillingness to avail itself and the public of the immediate opportunity to collect site-specific fishing and consumption data for the Study Area in favor of default values that are based on studies of areas with inapposite characteristics does not comport with EPA practice and guidance. We urge that EPA remain always mindful that any remedial action at this Site is quite likely to be extremely costly and to pose significant implementability challenges. Accordingly, if site-specific data can provide confidence that a risk estimate is realistic for and representative of the Study Area, and that the remedy selected is health protective, it will greatly improve EPA's decision making and defense of same.

During our May 23, 2000, meeting, EPA sought to justify its reversal by saying not that it would be "impossible" to conduct a valid Creel/Angler Survey (indeed, EPA officials conceded that it is not impossible, contrary to the assertions in the April letter), but rather that EPA inexplicably believes it would take up to four years for the Survey to be completed. This simply is not the case, and CLH explained why the scheduled fifteen-month program is a reasonable estimate of the time required for the survey. As noted above, EPA's January 28, 2000, letter set forth a schedule under which these survey data are to be submitted by July 31, 2001; CLH was fully in agreement, with the understanding that EPA would approve the survey Work Plan by February 18.

The key reasons expressed by EPA at our meeting as to why the Creel/Angler Survey would take so long were CLH's lack of information regarding fishing locations and preferred fishing times, and lack of community outreach. We respond to these assertions as follows:

Lack of Information on Fishing Locations/Times

The Passaic River Study Area is small compared with the area encompassed by the Newark Bay studies of Dr. Kerry Kirk Pflugh.

	Water Area	Shoreline
Kirk Pflugh Study	12.7 sq. miles	132 miles
Passaic River Study Area	0.56 sq. miles	13.0 miles

This comparison demonstrates a 10-fold difference in area and a 20-fold difference in shoreline that needs to be surveyed.

The CLH team has extensive knowledge of the Passaic River Study Area and has observed fishing locations. Members of CLH's team, from the Project Manager to individual consultants involved in the development of the draft Creel/Angler Survey Work Plan and those who will be employed to supervise the conduct of the survey, have many years of experience on and around the Passaic River. We can confidently say that members of this team know virtually every possible fishing location within the Study Area. Further, these team members have worked the 6-mile Study Area during pre-dawn, daylight, and post-dusk hours for many years and some have been working on the River for more than 10 years.

The draft Creel/Angler Survey Work Plan provides for interview teams to work 100 out of 365 days, thus far surpassing the effort of the Kirk Pflugh study referenced by EPA.

The draft Creel/Angler Survey Work Plan presents a quantitative evaluation of the number of survey events/times. Appendix B of the Work Plan presents a detailed statistical analysis and discussion that supports the proposed survey schedule (*i.e.*, number of survey days and times), and indicates that under likely river use scenarios, no substantial populations of anglers will be "missed" by the survey effort. In addition, as documented in the draft Work Plan at pages 3-13 and 3-14, the team planning the Creel/Angler Survey contacted local merchants who serve fishing needs and other persons knowledgeable about local fishing. From these contacts, the team learned that fishing effort largely is confined to stretches of the river upstream of the Study Area; however, there is limited fishing/crabbing that takes place in the northern portion of the Study Area, in particular at the Hess station in Harrison. The team also learned that fishing effort is higher on weekends and during the spring when striped bass appear in the River, and during periods when crabs are active in the River. No particular time of day was mentioned as having higher fishing effort than any other.

Lack of Community Outreach

EPA's criticism of CLH's lack of community outreach was based on the Kirk Pflugh study that used such an approach. It was suggested that CLH would not get valid responses without involving the community prior to the field survey. During subsequent discussions it was understood as to the Kirk Pflugh study that:

1. Community outreach was the purpose of Kirk Pflugh's investigation.
2. Community outreach prior to a creel/angler survey would bias the responses of anglers.

3. Kirk Pflugh's outreach to community groups had no impact on actual anglers – in fact, during the field portion of Kirk Pflugh's study, local anglers did not know of the survey until the survey team had been seen working the area for more than 2 weeks.
4. The key to successful angler responses was to use young female interviewers, not to let the anglers know that the survey was being conducted by the State, and to let the anglers see the survey teams repeatedly.

Based on Kerry Kirk Pflugh's experience as related at our meeting, we conclude that a lengthy advance program of interaction with community groups would be ineffective at targeting anglers and consequently would not enhance the success of the on-site survey. Based on Dr. Kirk Pflugh's comments, and recognition that the community being targeted is the fishing community, the on-site survey's pretesting phase and the survey itself represent the "community outreach" that will be most effective in building a positive relationship with the anglers, thus securing their cooperation with the survey activities.

In summary, CLH has a robust, practical knowledge of the fishing sites in the Study Area and a demonstrated statistically valid plan for covering all fishing times during which survey crews can safely conduct interviews. Therefore, CLH maintains that the planned 15-month survey, which includes three months of pre-testing and the full-scale, four-season survey, is properly designed and will succeed in collecting the required input data for the risk assessment.

Conclusion

We are very troubled that EPA, having taken nineteen months (October of 1996 to April of 1998) to review and comment on the draft ESP/CSO Addendum and having taken ten months from June of 1999 until April of 2000 to formally respond to the Creel/Angler Survey Work Plan (a review total of nearly as many months as will be required to conduct the survey), now wants to skip the very crucial step of collecting site-specific angler and consumption data. We believe that EPA, having unfortunately consumed so much time that could have been used to finalize the Work Plan, pretest it, and even to have gotten well underway with the data collection, now seeks to hasten the conduct of the HERA in the absence of the site-specific angler and fish consumption data that CLH is ready, willing, and eager to collect. We are forced, reluctantly, to conclude that EPA has decided to drive risk assessment to results that are not representative of, and may not be defensible with respect to, the Passaic River Study Area.

We respectfully request that EPA reconsider its April 2000 directive to forego collecting site specific angler and fish consumption data and that it revert to its long-standing determination of the necessity to collect site-specific data (which comports with EPA guidance, unlike this recent reversal) and work with CLH to complete this essential data collection.

Patricia Hick, Esq.

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June 16, 2000

Please be advised that CLH disagrees with EPA's April 2000 directive. If EPA does not reverse this determination, CLH nonetheless will move forward to finalize the Creel/Angler Survey Work Plan and to conduct the site-specific Survey. This study will be conducted in a manner that is responsive to all of EPA's comments received to date to assure the quality and validity of the results for future use.

Under the AOC, EPA and CLH have a general duty to "make reasonable efforts to informally and in good faith resolve all disputes or differences of opinion." AOC ¶ 90.

Please include this letter in the formal administrative record for the Diamond Alkali Superfund Site Operable Unit II, along with CLH's May 26, 2000 letter and the accompanying documents submitted by Mr. Firstenberg.

Very truly yours,



Carol E. Dinkins

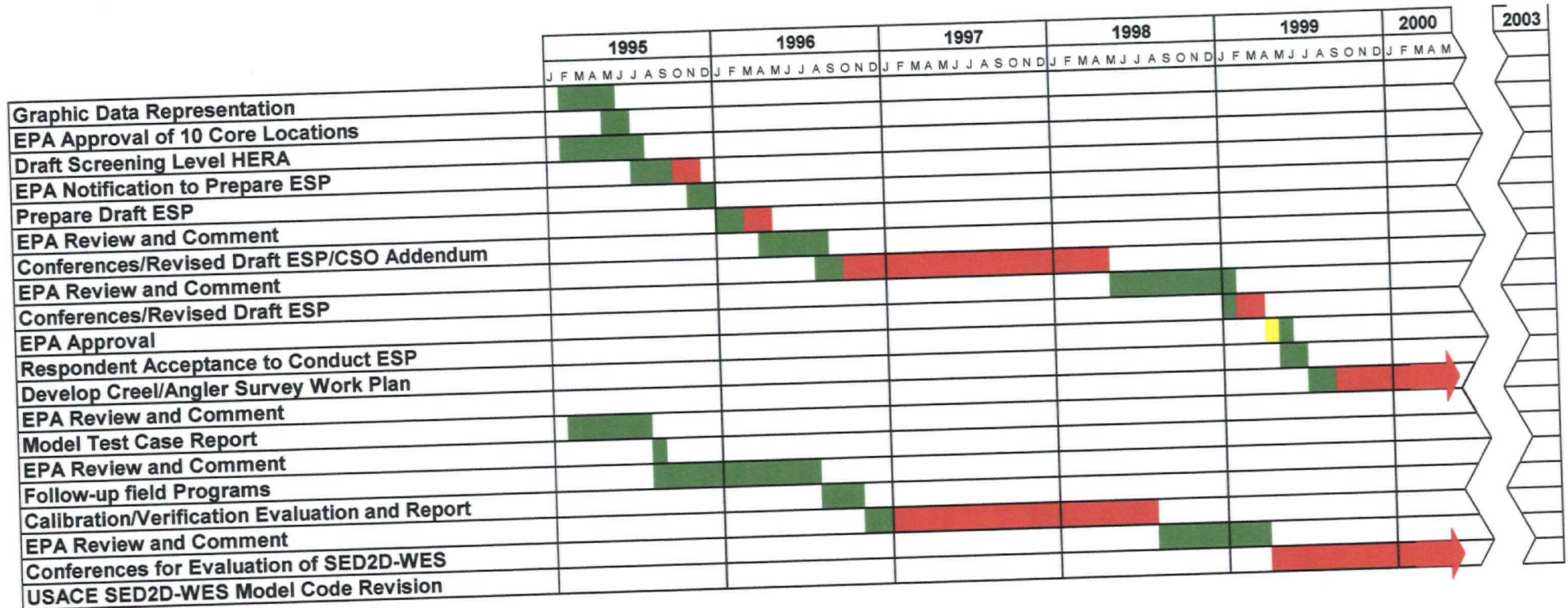
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cc: Mr. Delmar Karlen
Ms. Kedari Reddy
Mr. Dave Rabbe
Ms. Corrine Hawkins
Mr. Clifford E. Firstenberg

enclosures: [list]

PASSAIC RIVER STUDY AREA **Schedule Variance to Date**



**Response to January 27, 2000 EPA Informal Comments
On the Draft Creel/Angler Survey Work Plan
(Prepared June 2000)**

Section 1.3.1.1 Site-Specific Risk Quantification Terms

1. Exposure events, page 1-6

Exposure events are described as fishing and/or crabbing outings (trips) to the Passaic River Study Area (SA). This may not be accurate, because a fishing event does not necessarily correspond to exposure. One fishing event may result in none or several consumption events. Consumption rate should not be directly linked or equated to fishing event since the relationship is variable.

In the Draft Creel/Angler Survey Work Plan (CASWP), the definition of an exposure event as a fishing and/or crabbing "trip" does not limit consumption to either the day of the trip or the person taking the trip. Rather, the trip is the basis for enumerating the total amount of exposure that results from that particular trip. Questions are asked about others who will eat the fish caught and kept on the trip, as well as about the number of meals that the catch represents and the portion size for the meals.

It is important to define the exposure events in terms of trips, since that is the most accurate basis for measurement in the on-site survey. Consumption of fish and/or crabs from the Study Area requires a fishing or crabbing trip, and so consumption is linked to fishing events. The relationship between consumption and trips is variable in the short term (i.e., consumption may vary across trips), but over the longer term the consumption rate is most accurately developed by (1) measuring the consumption derived from fish and/or crabs caught and kept each observed trip, and (2) collecting information on the number of trips taken in a given period.

It appears that the Draft CASWP was misinterpreted on this topic. However, the text of the revised CASWP has been modified for clarification.

2. Consumption Rate, page 1-7

This term is described as the amount of fish eaten by the individual (angler) per exposure event. However, consumption rate must be calculated for whole households, because most anglers share their catch with family members, e.g., one fisherman can correspond to several exposed individuals, some of which likely represent the higher-risk population (see below).

In the Draft CASWP, the term "individual" does not refer only to the angler, it refers to the angler and/or anyone who consumes the angler's catch.

Per the explanation provided, there are no modifications required to the Draft CASWP to address this comment.

3. Averaging Time, page 1-7

For non-carcinogenic effects, the exposure time should not be limited to exposure duration (defined as a fishing event). The high-risk group is women of childbearing age and children under the age of 15. Potential health effects to this population are reproductive disturbances and neurological and development problems. As proposed, the averaging time for these very real and serious health effects are not addressed.

CLH agrees that for assessing non-cancer health effects the averaging time should not equal the period of a trip. Averaging time is equal to the period over a lifetime when exposure takes place. The Draft CASWP defines averaging time as equal to the exposure duration (i.e., the number of years the angler fishes and/or crabs in the Study Area). In the survey, anglers are asked (1) when they first fished or crabbed in the Study Area, (2) if they fished or crabbed each year since then, and (3) if the answer to (2) is no, the number of years in the last five years that they fished or crabbed in the Study Area.

The existence of sensitive populations, such as children or women of childbearing age, does not change this approach. The exposures for these populations from consuming fish from the Study Area are determined from those who fish and/or crab in the Study Area and share their catch with the household. The period of exposure is coincident with the period over which the sharing takes place, and therefore is captured in the Creel/Angler Survey (CAS) as previously described.

It appears that the Draft CASWP was misinterpreted on this topic. However, the text of the revised CASWP has been modified for clarification.

Section 1.3.1.2 Site-Specific Risk Characterization Terms

4. Household Survey, page 1-8

- a. The NJDEP has already done a Statewide household fish consumption survey from which to draw information from.*

Throughout the process of developing the ESP that began in 1995, CLH has requested of EPA and representatives of NJDEP that they provide any relevant materials (e.g., reports, publications, data) that are pertinent to the CAS. However, the information provided to date is limited to referrals to EPA's 1997 *Exposure Factors Handbook*, and the urban angler studies conducted by Dr. Kerry Kirk Pflugh (NJDEP) and colleagues in the Newark Bay Complex. In addition, CLH's representatives conducted a literature search and compilation for information relevant to the development of the Draft CASWP. As a result of these efforts, CLH is not aware of any household fish consumption surveys conducted in New Jersey that have specifically collected and segregated data from those individuals using the Study Area, or that have been specifically tailored to populations in the Newark area that may fish and/or crab in the Study Area.

Because this information was not provided to CLH and is not in the public domain, it could not be considered in the revised CASWP.

- b. *The household telephone survey is not expected to be successful in getting an accurate picture of individuals who are fishing and consuming fish in the PRSA because the population of people fishing and crabbing in the PRSA is expected to be small as compared to the overall urban population. Therefore, the likelihood of contacting those households that do (through a random calling scheme) is low.*
- c. *In addition, without a local civic or community interest group or club being involved on some level to endorse the survey or otherwise encouraging participation in the survey, people are less likely to agree to participate.*
- d. *Much of the information slated to be obtained through the household survey could best be obtained via the intercept survey. For example, data pertaining to features that are attractive for fishing is best obtained from the individuals found to be fishing and crabbing.*
- e. *Finally, many in the population of concern may not have phones. Instead, the intercept survey, if conducted correctly, will be more successful in getting this information, combined with census information for the local communities.*

CLH accepts EPA's comments and concerns regarding the proposed household survey described in the Draft CASWP. While CLH believes that a valid and useful household survey can be conducted to meet the data use objectives stated in the Draft CASWP and ESP, we believe that working through the details of such a survey with the Agency would require a great deal of time and effort and, as such, would jeopardize our ability to begin to implement the more important on-site survey this summer. As a result, the household survey has been removed from the revised CASWP, and the on-site survey has been modified to obtain the information that was planned for collection in the household survey. These modifications include performing boat-based counts of anglers present in the Study Area during the intercept survey periods.

- f. *In addition, the DSRT already conducted a statewide study that compares consumption rates and practices with the intercept (angler) population. A copy of this study is available upon request to the Department.*

This comment has already been addressed. Please see CLH's response to comment 4.a above.

Section 1.3.2.1 Site-Specific Risk Quantification Terms

5. Consumption Rate, page 1-9

This should include crabs, not just fish, as most anglers keep crabs, not finfish.

CLH agrees and always intended that the consumption rate for the Study Area must include crabs as a key component. However, it should be noted that the statement the Agency makes in this comment "most anglers keep crabs, not finfish" can only be

substantiated by a site-specific study. The questions asked in Appendix A of the Draft CASWP (now Appendix B of the revised CASWP) allow consumption rates to be computed for both fish and crabs.

It appears that the Draft CASWP was misinterpreted on this topic. This comment is already addressed using questions contained in the Draft CASWP. Therefore, no modifications to the Draft CASWP are required to address this comment.

6. *Section 1.4.1 The On-Site Survey, page 1-13*

- a. *In several locations, the CASWP states that the goal of the on-site survey is to determine whether subsistence populations use the PRSA. However, the goal should be to determine whether consumers are using the PRSA, subsistence or otherwise. Previous Department studies show that many who fish and crab in this area do so to either supplement their food source or for opportunistic reasons (sell their catch), rather than subsistence fishing/crabbing.*

CLH agrees with this comment. As stated on the first page of the Draft CASWP, the goal of the CAS is to collect data for a human health risk assessment conducted in accordance with EPA's *Risk Assessment Guidance for Superfund* (USEPA, 1989). The data collected will be used to determine fish and crab consumption rates for all Study Area anglers. However, the identification of any subsistence population that may be using the Study Area is one important objective of the on-site survey, as is consistent with EPA guidance regarding the conduct of fish and wildlife consumption surveys (USEPA, 1998).

It appears that the Draft CASWP was misinterpreted on this topic. However, the text of the revised CASWP has been modified for clarification.

- b. *In addition, the time of day during which fishing occurs is not random, therefore the random sampling approach as proposed will produce a biased low sample. The random approach as proposed may miss the population of concern, or it will be grossly underestimated, because the population of concern fish at optimum times such as when the tide is coming in or going out, and often at night (between the hours of 6 to 9 pm during the warm weather season). Therefore, optimal fishing and crabbing times should be targeted as the preferred times of conducting the intercept survey. As a start, the intercept survey should be done during the months of mid to late May through the end of September to maximize the frequency of encountering people fishing and crabbing in the SA.*

Observations made during multiple site-visits and other sampling activities conducted under the ESP, including during the hours from dawn through about 8 p.m. during the summer, show that individuals use the Study Area primarily during the middle of the day, and much less so very early or late in the day. Additionally, based on these same observations, there does not seem to be a pattern of fishing related to the tide in the Study Area. However, in order to ensure that no daylight hours are missed in the CAS, CLH has made the following modifications to the revised CASWP.

For each sampling day, the total number of daylight hours will be determined, and that day's sampling duration will equal half of the daylight hours rounded up to the nearest hour. For example, at the summer solstice, there are approximately 15 hours of daylight; hence, an 8-hour sampling period will be used. In the winter, the minimum sampling period will be 5 hours. The half sampling period will be randomly selected to either begin at dawn or end at dusk, thus ensuring complete coverage of all daylight hours and tidal regimes repeatedly over the course of the study.

The CAS allocates sampling effort to the full year, but emphasizes the May to September period. An assumption that summer consumption rates are representative of the full year may lead to an overestimate of consumption in the winter; conversely, an assumption that there is no fishing in the winter, and that consumption is zero, may underestimate consumption. It appears that the Draft CASWP was misinterpreted on this topic. The concern raised by EPA in this comment was already addressed in the Draft CASWP. Therefore, no modifications to the Draft CASWP are required to address this comment.

General Comments

7. General Comment 1

- a. *The work plan does not clearly address how the data obtained from the two surveys will be ultimately used.*

As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

The Draft CASWP identified the data to be collected under the CAS, as well as the risk assessment elements the data were intended to support. However, in order to be responsive to this comment, CLH has included an expanded discussion regarding the risk assessment uses of the CAS data in the revised CASWP.

- b. *The objectives of the on-site survey versus the objectives of the telephone survey need to be clearly specified.*

As discussed in CLH's response to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP. The Draft CASWP clearly specifies the objective of the on-site survey. Therefore, no modifications to the Draft CASWP are required to address this comment.

- c. *The telephone survey seems to be focused on fishing habits as opposed to eating habits.*
- d. *It seems that both surveys will be identifying two populations (one may be a subset of the larger population of residents near the Study Area).*

As discussed in CLH's response to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

- e. *In addition, one question that seems to be missing from both the on-site survey and the telephone survey is the knowledge about fish advisories and/or fishing bans (see number 2, below).*

In order to be responsive to this comment, questions have been added to the on-site survey in the revised CASWP to allow quantification of possible effects of advisories on fish consumption, following the approach of West et al. (1989). For further clarification, please see CLH's response to comment 8 below.

8. *General Comment 2*

The report fails to address the current fish consumption advisory for the river that was instituted based on the high levels of contamination. This will tend to bias the results lower, and may potentially underestimate the risks posed by the site. Since under the Superfund program we are responsible for evaluating risks to the Reasonably Maximally Exposed individual under both current and future exposures and in the absence of any institutional controls (i.e., fish advisories) it is doubtful that this survey will provide adequate information for the determination of fish consumption patterns in the absence of fish advisories.

It is not typical to build questions into creel and angler surveys that deal with "fishing in the absence of a fishing ban" (i.e., the issue of "suppression"), even though most of the surveys that have been conducted in the U.S. (including those at other CERCLA sites), and upon which EPA relies for deriving its information regarding fish consumption habits, have occurred in waterways that have institutional controls in place. The issue of "suppression" is typically dealt with in CERCLA risk assessments qualitatively in the uncertainty analysis.

Following receipt of a similar comment from EPA as part of the Agency's comments (dated April 15, 1996) on the December 1995 Draft Ecological Sampling Plan, CLH's representatives reviewed the available literature related to suppression to determine the potential impact to an accurate risk assessment (the primary reason for conducting the CAS). Based on this review, and discussions with Dr. Kirk Pflugh regarding her study of people's perceptions of fishing advisories in the Newark Bay Complex (surrounding the Study Area), CLH determined that the existence of fishing advisories would not impact the accuracy of the risk assessment.

Following receipt of this comment, CLH again re-visited this issue. Two recent publications by Dr. Kirk Pflugh and colleagues, and Dr. Burger and colleagues, presented the results of a study on people's perceptions of fish consumption advisories in the "Newark Bay Complex." The results of their research clearly indicate that institutional controls do not appear to have an effect on people's fishing or crabbing behavior in the Newark area.

Only one published study, entitled *Michigan Sport Anglers Fish Consumption Survey. A Report to the Michigan Toxic Substance Control Commission*, produced by West,

P.C., M.J. Fly, R. Marans, and F. Larkin under Michigan Department of Management and Budget contract No. 87-20141 in 1989, attempted to measure the impact of fishing advisories on people's consumption habits. West et al. (1989) demonstrated that the likely adjustment to consumption rates from "suppression" was very small (an increase of about 6 percent), and was substantially less than the downward adjustment that is needed due to "non-response bias" from the survey (a decrease of about 12 percent). Based on these results, "suppression" effects appear to be a relatively small part of the overall variability inherent in creel and angler surveys. Thus, specific questions to deal with "suppression" will not yield useful results.

More importantly, the results of Dr. Kirk Pflugh's study have clearly demonstrated that fishing advisories do not suppress the fishing or crabbing activity in Newark area waterways. Therefore, the results of Dr. Kirk Pflugh's study, upon which EPA relies in its comments on the CAS, should alleviate the Agency's concern regarding this issue.

For these reasons, CLH did not include questions addressing "suppression" in the Draft CASWP. However, based on this comment, and comments made by the Agency during the meeting that was held between EPA and CLH on May 23, 2000, it is clear that this issue is still important to EPA. Therefore, CLH has added specific questions to the revised CASWP to attempt to measure the reduction in consumption, if any, from fishing advisories. These questions follow the approach of West et al. (1989).

9. *General Comment 3*

- a. *The report fails to provide information on existing creel surveys either within this geographic area or within New Jersey. At a minimum, this data should be reviewed. A thorough explanation regarding why this data is not being used, should also be presented.*

A review of the published information regarding creel and angler surveys in New Jersey was conducted during the development of the Draft CASWP. In response to this comment, a focused summary of available literature regarding existing creel/angler or other fishing-related surveys in the geographic area surrounding the Study Area has been added to the revised CASWP. In addition, explanations regarding the uses and limitations of this information are provided in the revised CASWP.

- b. *Further, in the Hudson River assessments, EPA used data from a statewide assessment of anglers that provided information on consumption patterns in the absence of fish advisories at other similar river bodies. It is suggested that a similar approach be considered for the Passaic River.*

The Hudson River assessment did not use data from water bodies absent fishing advisories; rather, it used data from other "similar" water bodies that have consumption advisories of a different nature than those on the Hudson. Neither

approach is possible for the lower Passaic River because, to our knowledge, there exist no other substantially similar water bodies to the Passaic (in terms of degree of industrialization of shoreline, shoreline access, and catchable fish populations), without consumption advisories, which have been the subject of a rigorous study of fish consumption. Therefore, no action can be taken to address this comment.

Furthermore, CLH has responded to the issue of “suppression.” Please see CLH’s response to comment 8 above.

c. Also, information on the fishing practices within the Passaic River, and the need for licenses, should also be presented in the document.

Fishing licenses are not required to fish or crab in the Study Area. In response to this comment, this has been clearly stated in the revised CASWP.

A general description of fishing practices in the area, based on the information from the study conducted by Dr. Kirk Pflugh and Dr. Burger in the Newark Bay Complex, as well as CLH’s field experience in the Study Area, appears in the revised CASWP. However, detailed knowledge of such practices for the Study Area can only be obtained via implementation of the CAS.

10. General Comment 4

a. It is also stated in the work plan that the (household) survey is needed to establish a description and comparison of the population in the area in order to compare the angler population. A simple demographic analysis of the communities in the Study Area will provide all the needed population information. This can be achieved by reviewing census data or by contacting each community to obtain specific population data.

Census data do not provide all the information needed for risk characterization; comparisons of the nearby population to the angler population using demographic data are only part of this effort. An estimate of the size of the population affected is also needed. This information will be developed by scaling up counts of anglers obtained during the on-site survey. As discussed in CLH’s responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

In response to this comment, CLH has added an explanation regarding this issue to the revised CASWP.

b. The Work Plan also states that a household survey is necessary to compare consumption practices and rates with the intercept population. NJDEP conducted such a study several years ago that can be utilized for that purpose. Kerry Kirk-Pflugh, of NJDEP, can provide a copy of that report (609-633-2312).

CLH's representatives have repeatedly requested a copy of the report referred to in this comment as well as related reports, but to date has not received any documents from NJDEP. For this reason, no action can be taken to address this comment.

11. General Comment 5

- a. The appropriateness and necessity for a household survey is questionable.*
- b. Certainly, it would be biased towards individuals who have phones. The subsistence population of concern in this area may not own phones.*
- c. Also, this approach does not address newer phone devices such as cellular phones and may not identify a significant portion of the population of concern.*
- d. The interview protocol suggested is adequate, however. But, this methodology is inappropriate.*
- e. A random telephone survey of the Study Area to describe and compare the population with the intercept population is not necessary. Personnel in the NJDEP Division of Science, Research and Technology, via their own research in this area and a review of literature, suggest that the phone survey will yield little or no information about the existence and use of recreationally caught fish by the general population in the Study Area. This is because the general population does not rely on local recreationally caught fish to support its household consumption of fish. It is NJDEP's position that the best way to find out who is fishing and consuming in the Study Area is to perform an intercept study.*

As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP. CLH agrees with NJDEP that the best method to assess fishing and fish consumption in the Study Area is to perform an intercept survey.

12. General Comment 6

The report fails to explain how the information from this survey will be used in the human health risk assessment. The logic presented regarding this issue throughout the report is confusing. It is strongly suggested, that a clear delineation of the uses of this data be identified in the document before conducting the survey.

This comment has already been addressed. Please see CLH's response to comment 7 above.

13. General Comment 7

The report fails to indicate any process for involving the community in the pre-testing or survey. This is a major shortfall of the process.

According to Dr. Kerry Kirk Pflugh of NJDEP, community involvement does not affect the implementation of fishing-related surveys in the Newark area. Dr. Kirk Pflugh's statements on this issue (made during the May 25, 2000 meeting held between EPA, NJDEP, and CLH) are based on her experience in conducting a pre-test and survey in water bodies surrounding (but not within) the Study Area. For this reason, CLH concludes that community involvement will impact neither the pre-test

nor the survey for the Study Area. In addition, CLH's representatives have extensive experience working in the Study Area, and have gained a clear understanding of the types of information (fishing locations, demographics, etc.) that EPA expects to gain from community involvement in the CAS process.

Since the beginning of the implementation of RI/FS field sampling activities in 1995, and particularly following receipt of EPA's comments on the Draft ESP, CLH's representatives have spent countless hours in the Study Area at various times of the year and day (with the exception of after dark hours). During this time, our representatives have observed, encountered, and in many instances conversed with people fishing and/or crabbing in the Study Area. From these encounters and observations, CLH has a clear understanding of the locations where people fish and/or crab in the Study Area and what types of species they are attempting to catch. It is this site-specific knowledge that formed much of the basis for the site-specific design of the CAS contained in the Draft CASWP.

Per the explanation provided, there are no modifications required to the Draft CASWP to address this comment.

14. General Comment 8

No protocol is provided for the HERA. This makes it difficult to fully determine how this information will be used in the analysis. Specifically, is a Monte Carlo Analysis planned in addition to the point estimate? If so, how is this expected to impact the collection of data?

The HERA protocol is not required for the CASWP. The objectives of the CAS are clear with respect to how the data will be used in the HHRA. The Draft CASWP clearly identifies the risk assessment uses of the data to be collected in the CAS. However, to be responsive to this comment, the revised CASWP includes additional information in this regard.

It is anticipated that a Monte Carlo approach will be used as discussed in the revised CASWP. It does not matter for the planned data collection whether a Monte Carlo or point estimate will be used in the HHRA, because the data to support either method are the same.

15. General Comment 9

Appendix E, page E-11 lists a number of concerns that may tend to underestimate fish consumption patterns in this area. It is still unclear why other methods were not considered to obtain the data necessary to assess fish consumption based on the potential negative results of this analysis.

The reason for this comment is unclear. Page E-11 lists health and safety precautions to be taken by the CAS interview teams. These will not bias survey results. EPA guidance (1998; 1992) clearly states that an on-site intercept survey is the best way to

collect information regarding consumption rates for a specific waterbody, and to identify subsistence populations.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

Specific Comments

16. Figure 1-1

The significance of the circle around the Newark Area should be identified in the text and the legend. Is this the area to be covered by the Creel/Angler Survey? If so, this should be identified in the document.

Figure 1-1 depicts the general area in which the Study Area is located. This figure has been modified for the revised CASWP.

17. Page 1-1

The report fails to describe the existing surveys in this geographic area as well as state-wide surveys. Of concern is the potential bias in the survey since adequate attention is not being applied to the current ban on fishing and associated health advisories in this area. It is important to have comparable studies with existing surveys that will allow a comparison of the results of this proposed survey, should it be carried out.

The issues raised in this comment have been addressed. Please see CLH's responses to comments 8, 9.a, and 9.b above.

18. Table 1-1

a. It is unclear whether existing questions from other surveys were considered in the development of the questions provided.

It is not clear to which surveys the comment refers. Existing published creel and angler studies, including those that were used by EPA to develop its default fish consumption rates, were carefully considered in the design of the CAS. Regardless, as specified in the Draft CASWP, the fitness of questions will be evaluated in the pre-test.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. Further, it is unclear whether forward or back translations will be conducted for the variety of languages that will be included in the survey. It is recommended that approaches used in the Hispanic Health and Nutrition Examination Survey to forward and back translate documents for the general public may be helpful in assuring that the translations are appropriate.

The extensive, multiphase translation procedures used in the Hispanic Health and Nutrition Examination Survey were appropriate for a large, nationwide study, but are

not necessary for a smaller study like the CAS, which covers only a very limited geographical area (about 0.56 square miles).

The survey instrument will be written in English, Spanish, and Portuguese, and administered in English, Spanish, and/or Portuguese. The appropriateness of the translations will be evaluated during the pre-test. On-site interviewers will be multi-lingual, speaking English, Spanish, and/or Portuguese. Other languages will be handled by real-time translation via telephone. To be responsive to this comment, this issue has been clarified in the revised CASWP.

19. Page 1-4

- a. *It is unclear what the minimum number of individuals required to participate in the survey is. A vague reference is provided in later sections of the report regarding the fact that a specific number of anglers is not necessary in the survey. Of concern is the potential for the small number of anglers to not be representative of the general population. It is suggested that minimum data requirements for the surveys should be identified, that a minimum tolerance for number of responses be identified so that decisions are not made based on a small N, and that a power calculation be calculated to identify the minimum number of responses necessary in the analysis for both the on-site and household surveys.*

The plan for the on-site survey specifies the sample size in terms of the amount of sampling effort (i.e., the number days of year and amount of sampling per day) rather than the number of individuals contacted. The latter is not a customary measure of sample size for intercept surveys where the size of the population is not known in advance. A minimum number of responses is not needed to be representative of the population in the on-site portion of the CAS.

The population cannot be enumerated before the survey; hence, power calculations of the type suggested cannot be undertaken. For example, if 5 individuals are intercepted, and the true population is 7, then a very large sample size has been obtained and statistical procedures have high power. If “only” 5 individuals are contacted but the true population is very large, the power of a given test is relatively low. The sampling plan is therefore stated in terms of the proportion of the dates and times interviewing will take place in order to intercept a large portion of the population of anglers, rather than a specific proportion of the population that will be contacted.

From this point of view, the “population” being sampled is the complete set of days and places where an interviewer could intercept individuals. A large sample size, then, is a large number of days to sample in a year, spending a large portion of each day sampling, and visiting a large number of places in the Study Area. Then, the probability that an individual who fishes or crabs in the target area is missed becomes small.

In the Draft CASWP it is proposed that 100 days of sampling is sufficient to give good coverage of the year. These days will be selected according to a stratified random sampling scheme to ensure coverage of all times when fishing and crabbing may take place. The proposed stratification approach based on months of the year and days of the month is well-established in the creel survey sampling literature. Sampling on one hundred days is approximately 27% of the primary sampling units (days of the year).

The proportion of sampling units being selected is considerably higher than is typical of creel surveys. Using monthly strata, Malvestuto et al. (1978) suggested that 45 sampling days was sufficient to accurately measure catch, with 5 days being allocated to the winter and the remainder to the summer. The sampling specified for the CAS is more than twice this amount in total, and provides more than three times the number of winter days. Malvestuto and Knight (1991) suggested that 6-days per month during the summer gave good estimates of total angling effort on a large lake with a convoluted shoreline that precluded complete instantaneous counts. The plan specified for the CAS has almost twice this much summer sampling effort. Newman et al. (1997) demonstrated good accuracy of a stratified creel survey as compared to a complete census using 20 hours per week of sampling effort during summer months. The plan specified for the CAS has more than three times this much sampling effort in the summer months.

The reason for sampling a substantial proportion of days in the year and portions of each day is to make sure that there is a low probability that people fishing and/or crabbing in the Study Area are missed by the CAS. In the Draft CASWP, a sampling simulation was employed to address this issue. The chances of missing an individual depends on the amount of time he or she spends in the Study Area, both in terms of duration of stay on each outing and the number of outings in a year. For example, a subsistence angler typically will spend a large amount of time in the Study Area relative to a casual recreational angler, and so the chances of missing a subsistence angler are relatively smaller.

In the Draft CASWP, the sampling simulation investigated the chances of missing what was called a "high avidity" angler. This angler was modeled as having a chance of visiting the Study Area that varied across season and days of the week. The high avidity angler visited the site 48 times per year in the simulation. Given 100 days of sampling and four hours of effort per day, there was only a 3% chance of missing this person, and on average, this person was intercepted more than eight times in the year. Since 48 times per year is relatively low visitation relative to possible subsistence fishing, the chances of missing a subsistence angler will be considerably lower than 3%. Furthermore, note that this is an absolute count of the number of trips, not the result of an estimate of the number of trips, so there would be less than 3% error in an estimate of trips from the sampling plan.

The number of planned sampling days in the proposed CAS is greater than the number of days spent sampling for a study that EPA relied upon to conduct a human

health risk assessment for fish consumption from another limited-access site. EPA used data collected over 64 days during the Santa Monica Bay Seafood Consumption Study from an area greater than 300 square miles. Comparatively, this proposed CAS would spend 100 sampling days in a portion of the Passaic River that is only about 0.56 square miles in area.

Consequently, if a small number of anglers are encountered in the survey, that is indicative that only a small number of anglers use the Study Area. The statistical design of the survey and the large amount of sampling effort ensure that the survey sample will, with high probability, be representative of the population using the Study Area.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- b. It is unclear from the description how the survey and approaches listed will address individual who both fish and consume crabs. Are separate analyses planned? Will they be combined for a subset of the population exposed? Will separate high end anglers for fish and crabs be identified? What percentile will be used in determining the RME population for both fish and crab consumption? These issues should be addressed in the analysis.*

As indicated in the Draft CASWP, the CAS will collect data on both fish and crab consumption from each survey respondent in the Study Area. The resulting data will be used to conduct a HHRA in accordance with EPA guidance. The specific use of the data will be determined when the exposure scenarios are developed following the implementation of the CAS. However, it is anticipated that a risk assessment will be conducted for fish consumption only, crab consumption only, and the combination of fish and crab consumption. In this context, appropriate risk descriptions will be specified (e.g., central tendency, high end).

It is improper to specify a given percentile of a specific or single input distribution that will be used for the RME for a particular exposure factor, which, according to EPA guidance, should represent exposure at or above the 90th percentile when all of the factors determining exposure are considered together. That is, the RME should be defined based on the output of the analysis, not the inputs to it, especially when it is unknown which are the most sensitive exposure factors.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

20. Page 1-6

- a. The distinction between exposure events and consumption of fish is unclear and further information regarding the basis for the separation should be provided.*

This comment has already been addressed. Please see CLH's responses to comments 1 and 2 above.

- b. It is also unclear why a distinction is made between fishing and crabbing when it is possible that a portion of the population of concern may consume both fish and crabs.*

CLH agrees that some people may catch and consume both fish and crabs. However, fish and crabs have different tissue concentrations of chemicals, are prepared differently, body parts are consumed in different proportions, and are typically consumed at different rates. The proportion of fish and/or crab in a given angler's diet is not known. For these reasons, fish and crab consumption need to be considered separately from each other in the risk assessment.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- c. Exposure events are described in the work plan as "fishing and/or crabbing outings (trips) to the Study Area." This may not be accurate, because a fishing event does not necessarily correspond to exposure. One fishing event may result in none or several consumption events. Consumption rate should not be directly linked or equated to fishing events since the relationship is variable.*

This comment has already been addressed. Please see CLH's responses to comments 1 and 19.b above.

21. Page 1-7

- a. The statements regarding the impact of seasons on activity patterns should be further delineated with appropriate references to support statements in the document.*

Statements in the Draft CASWP regarding seasonality of fish availability were derived from information provided by Dr. Robert Papson, a New Jersey state fish biologist (via personal communication with CLH's representatives). Detailed information regarding seasonality of fishing and crabbing for the Study Area is not available to our knowledge. Prior surveys in the region were only conducted during summer months (e.g., Kirk Pflugh et al. (1999) and May and Burger (1996)).

CLH has provided further clarification regarding the seasonality issue in the revised CASWP.

- b. It appears that the consumption rates are event specific but the statement that they will be defined based in part on fish consumption is inconsistent with the exposure assessment where the assessment is based on meals consumed.*

CLH agrees with this comment. The basic components of consumption rate are grams per trip per consumer, and number of trips. The text of the revised CASWP has been modified to correct the inconsistency.

- c. *It is unclear how, based on the literature, information on fish parts consumed will be used in the assessment.*

Anglers may not consume the entire fish or crab that they harvest. For example, anglers do not typically consume the internal organs of a fish. As discussed in the Draft CASWP, the survey will collect information on the parts of the fish or crab that will be consumed. Therefore, of the total amount of fish or crab harvested, the amount of fish or crab that is to be consumed can be calculated.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- d. *The discussion regarding the application of fish cooking methods to determine concentrations in fish is inappropriate. Will a determination be made regarding the concentration of specific contaminants in the fish when not all fish cooking methods have been ascertained in the scientific literature. Further, not all fish cooking methods result in a loss of contaminants as suggested in the statements. To address the potential for individuals to consume pan drippings, it is recommended for the RME point estimate that no attempt be made to adjust the consumption based on cooking practices.*

This is an issue that will be addressed in the HHRA protocol. The magnitude of the health risks from exposure to chemicals in fish or crabs is entirely dependent on the amount of chemical actually ingested and absorbed rather than the amount originally present in the individual species. Therefore, because most anglers will cook their fish or crab prior to consuming it, the reduction of chemicals in the fish or crab due to cooking must be taken into account. While some cooking methods may not result in a reduction and others have not been studied, reductions, if appropriate, will be applied for each cooking method used by the surveyed anglers.

In response to this comment, the survey instrument in the revised CASWP has been modified to include a question regarding the use of pan drippings. The information will be considered in estimating chemical losses due to cooking. The text of the revised CASWP has been modified to clarify this point.

- e. *The term consumption rate is described in the work plan as the amount of fish eaten by the individual (angler) per exposure event. However, consumption rate must be calculated for whole households, because most anglers share their catch with family members, e.g., one fisherman can correspond to several exposed individuals, some of which likely represent the higher-risk population.*

This comment is a duplicate of comment 2.

22. Page 1-8

- a. *What criteria will be used in determining whether a subsistence population exists? How many individuals will need to be evaluated to make this determination?*

In practice, the primary concern of risk assessors is so-called “subsistence” subpopulations. Subsistence subpopulations are defined in practice as groups of anglers who depend on fishing or crabbing to provide a consistent source of food. This theoretical dependence on fishing or crabbing for food leads to the expectation that subsistence anglers would have fish or crab consumption rates exceeding those of anglers whose interest in fishing or crabbing is recreational. Because the dependence on fishing or crabbing for food is assumed to be either economic or cultural, income or ethnicity characteristics of anglers are used to identify potential subsistence subpopulations.

Specifically, the information obtained from the on-site survey will be examined by using the following two approaches: 1) those anglers who consumed a noticeably higher amount of fish or crab would be identified and their data analyzed to determine whether they share a common trait (e.g., ethnicity, income) and 2) those anglers who shared a common trait would be identified and their data analyzed to determine whether their fish or crab consumption differs from that of the general angler/crabber population. No predefined number of anglers is required to perform this analysis.

In response to this comment, these points have been further clarified in the revised CASWP.

- b. *Approaches to address potential biases associated with fish consumption in the presence of fishing advisories should be included in the analysis.*

This comment has already been addressed. Please see CLH’s responses to comments 7 and 8 above.

- c. *The exposure event description is unclear since it does not address the number of trips that may occur in the absence of a fishing advisory/ban.*

This comment has already been addressed. Please see CLH’s responses to comments 7 and 8 above.

- d. *Since the survey is limited to one year, how will the data be used to address potential changes in activities with time.*

The total number of years a person fishes in the Study Area is determined in either two or three questions, depending on the “skip pattern.” First, the number of years ago that they first fished and/or crabbed in the Study Area is asked. Then, they are asked if they fish and/or crab in the Study Area each year; if the answer to that

question is no, then they are asked how many of the last five years they have fished and/or crabbed in the Study Area. These three questions will be used to determine the number of years that a person has fished and/or crabbed or will fish and/or crab in the Study Area in their lifetime.

None of the studies that form the basis of EPA's default fish consumption rates were conducted over a period longer than 12 months. As is generally the case, multi-year data will not be available from the Study Area and the assumption will be made that the range of behavior captured in the one-year survey is representative of subsequent behavior. This is the same assumption used in other CERCLA risk assessments approved by EPA that were based on creel and angler survey data (e.g., Palos Verdes Shelf, Lake Hartwell, Commencement Bay).

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- e. Since a fishing advisory/ban is in place the planned weighing of caught fish does not seem appropriate and consistent with recommendations regarding not consuming fish. This raises ethical questions regarding whether the people conducting the survey should provide education materials and advice to the angler regarding the consumption of the fish.*

For clarification, consistent with typical creel survey practice, the plan is to measure fish lengths, not weights. Regardless of the advisories and level of adherence to them, it is necessary to obtain these data to support an accurate risk assessment.

The survey population will be best served by unbiased results of the CAS. Our goal in this study is to make accurate measurements to be used for risk assessment, not to disseminate information.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

23 Page 1-9

- a. The stated question is not appropriate. The real question is how long an individual has fished or crabbed in general not just in this study area?*

CLH disagrees with this comment. The issue being addressed in the CAS, and ultimately in the HHRA, is the incremental exposure to contaminants in fish and crabs caught from the Study Area, not exposure to contaminants in general.

Therefore, CLH believes that the question is appropriate as stated and, as such, no action is necessary to address this comment.

- b. Considering the publicity regarding the site, and health advisories, it is possible that an individual will go to other areas to obtain adequate fish. If the ban was*

not in place, this individual may consume all of their fish from this river which will not be reflected in the analyses as stated. This bias should be addressed in the assessment to assure that consumption rates are not underestimated.

This comment has already been addressed. Please see CLH's responses to comments 7 and 8 above.

- c. The references to the studies that will be developed by ESP and the selection criteria for these studies should be presented in this report.*

The studies referred to are being conducted under the ESP and will be used to determine concentrations of contaminants in various parts of fish and crabs; the selection criteria for those studies are part of the HHRA, which is outside the purview of the CAS. Therefore, no action is required to address this comment.

- d. Will the individuals be interviewed at the end of the fishing trip? How would you know how much they will catch that day if the interview is conducted at the beginning of the fishing trip?*

Use of a roving intercept survey rather than a fixed point interview scheme was adopted in the Draft CASWP to maximize the number of anglers who could be counted and interviewed in a given amount of survey time. There is, however, a trade-off in that some interviews will contain only partial trip information.

In consideration of this comment, the sampling approach adopted in the revised CASWP is a hybrid approach that includes some interviews with anglers who have completed their trips. The information from complete trip interviews will be used, along with standard parametric approaches supported in the statistical literature, to estimate complete trip data for individuals for whom only partial trip data were collected via the roving intercept approach.

- e. How would you get at the number of years that the individual will be fishing from the area in the future?*

This comment has already been addressed. Please see CLH's response to comment 22.d above.

24. Page 1-10

- a. The on-site survey does not address non-responders. What is the minimum number of responses necessary to properly assess exposures? What approach will be used if an adequate number of responses is not available?*

Initial non-responders will be addressed with a non-response conversion protocol. Non-responders from the on-site survey will be compared to responders via demographic information obtained by observation.

CLH anticipates little non-response from intercept surveys. Other intercept studies have response rates of around 75% (e.g., Kirk Plugh et al., 1999), and we expect similar results. Information on non-responders can be obtained visually, including sex, ethnicity, and age.

The issue of the minimum number of responders required has also been addressed in response to comment 19.a above.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. For the household survey, what criteria will be used to define ethnicity? How will the existing of fishing advisories be addressed?

As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

c. The assessment should be based on fishing practices not just within the study area since in the absence of bans, the individual angler may consume larger amounts of fish and crabs from this area.

This comment has already been addressed. Please see CLH's responses to comments 7 and 8 above.

25. Page 1-11

a. How will the surveys address conducting the surveys in languages other than English? Will forward/backward translations be used? What plans will be used to check the adequacy of the language and questions used in the survey?

Both of the issues raised in this comment have been previously addressed. Please see CLH's response to comment 18.b above.

b. What pre-testing including schedules are planned?

Pre-testing will take place during the 4 weeks prior to the initiation of the CAS. Pre-testing will include conducting interviews with individual focus groups to determine the adequacy of the survey instrument, as well as a field test of the questionnaire. In response to this comment, additional detail regarding the pre-test protocols has been added into the revised CASWP.

c. How were the surveys presented in Appendices A and C developed? What changes were made from the original surveys and why? What questions are specific for the Diamond-Alkali site? This should be provided in the document.

As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

The surveys were developed using experience, expert opinion, general survey design principles, and EPA guidance on collecting site-specific fish consumption data. Other creel-angler surveys were reviewed, including those discussed in EPA (1998). The original surveys were used as a broad guide; they were altered to improve them based on current practices and site-specific factors, field observations, and qualitative research.

Questions refer to use of and consumption of fish from the entire Study Area as distinct from other locations in the region; no questions are specific to the Diamond-Alkali site at 80 Lister Avenue as this site has no relevance to the goals of the CAS.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

26. Table 1-1

a. *The exposure does not address future fishing practices.*

This comment has already been addressed. Please see CLH's response to comment 22.d above. For further clarification, it is customary to limit survey questions to events that can be observed or accurately recalled to avoid inaccuracies inherent in speculation regarding the future.

b. *Data to support an organ specific analysis including cooking methods does not exist and is not being collected in the ecological risk assessment. Therefore, how will the collected data in fish organs be used in the calculation of dose and risk/hazard?*

This comment has already been addressed. Please see CLH's response to comment 21.d above.

c. *The term ethnicity is not defined nor are populations identified in the document. This should be provided.*

Ethnicity refers to membership in a particular racial or cultural group. In the Draft CASWP, the groups used to classify the ethnicity of respondents are: White, African American, Hispanic, Asian, Portuguese, Native American, and Other.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

d. *Similarly, the term subsistence angler should also be defined within the context of the population being evaluated in this assessment*

This comment has already been addressed. Please see CLH's response to comment 22.a above.

e. *The term “site features” should also be defined.*

Site features are descriptive quality characteristics of fishing sites, such as degree of shoreline development, access, expected fishing success, etc.

In response to this comment, a description of these Study Area features has been included in the revised CASWP.

27. *Page 1-13*

a. *The criteria that will be used to identify the “well defined subpopulation” should be presented in the document.*

This comment has already been addressed. Please see CLH’s response to comment 22.a above. For further clarification, because this is a data analysis issue for the HHRA, it need not be specifically addressed in the CASWP.

b. *Future activities should also be included in the document.*

It is very difficult to obtain accurate responses about predicted future behavior in a survey context. We will infer future behavior from past behavior as described in CLH’s response to comment 22.d above. For this reason, no action is required to address this comment.

c. *What is the basis for the 1 month recall approach? Why wasn’t a diary method adopted?*

A one-month recall period has been shown in the literature to be a period in which recall is accurate, and represents standard practice.

With respect to on-site intercept surveys, diary methods are impractical and are impossible without re-interview of the same subjects, which is not assured in the on-site survey.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

d. *It is unclear how the household survey using random digit dialing will address cellular phones, etc?*

e. *How will it address individuals without phones that maybe more likely subsistence anglers?*

f. *No information regarding the number of people needed in the survey to have a representative population is provided.*

As discussed in CLH’s response to comment 4.b through 4.e above, the household survey has been removed from the revised CASWP.

- g. No information regarding the manner in which the data will be analyzed, and how this information will be applied in the risk assessment is included in the document.*

For purposes of the CASWP, data analysis consists of descriptive statistical analysis of survey responses. How we anticipate that the information generally will be used in the risk assessment is described in CLH's response to comment 7 above. Final HHRA protocols will be developed following completion of the CAS.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- h. Also, will the data be provided to EPA for its evaluation? If so, what is the planned format for this analysis?*

Section D.5. of the Draft CASWP describes data storage and compilation procedures for the CAS. Following collection, data entry, and appropriate quality assurance/quality control evaluation of the data, EPA and NJDEP will be given the CAS database. Data will be provided in a standard database format, such as an Excel spreadsheet file or in Microsoft Access.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- i. Further information on how this data will be used in the risk assessment should be included in the report.*

This comment has already been addressed. Please see CLH's response to comment 7 above.

- j. Should the day of the interview be randomly selected or should they get there when people are more likely to fish?*

The day of interview is being randomly selected from month and weekday/weekend strata with known probabilities of selection. However, the selection probability is higher when it is believed that individuals are more likely to fish or crab in the Study Area. Please see CLH's response to comment 6.b above for further clarification on this issue.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- k. What happens if there is bad weather?*

Weather days will be defined by the field supervisor based on personnel safety considerations. If no sampling takes place on that day, then the effort will be re-drawn from the same strata.

On days where incomplete sampling takes place (i.e., reduced sampling days), the data collected will be used. There will be a maximum number of reduced sampling days allowed, after which they will be replaced from the remaining days in the strata by random draw. The maximum number of reduced sampling days will be four in the summer, three each in spring and fall, and two in winter.

In response to this comment, this issue has been clarified in the revised CASWP.

28. Page 2-1

The statement "Detailed HERA protocols can not be determined at this junction because such protocols must be designed to use [sic] the data collected in the CAS" is not appropriate. The objectives of the application of the data in the HERA should be determined first, and the data collected should be designed to meet these objectives. It is not appropriate to collect data without first clarifying how to use it in the assessment.

This comment has already been addressed. Please see CLH's response to comment 7 above. For further clarification, the design of the CAS has considered the risk assessment needs and has been modeled after other such surveys (including those used by EPA at other CERCLA sites) that were designed specifically to support risk assessments.

29. Page 2-2

a. How will the data collected by organ and cooking practice be included in the stated equation?

This comment has already been addressed. Please see CLH's response to comment 21.d above. For further clarification, the information on loss of chemicals due to cooking will be used to modify the concentration term in the referenced equation. These clarifications have been made in the revised CASWP.

b. How will data in fish and crabs be defined?

This is a confusing comment. We assume it is asking whether data on fish and crab consumption will be considered separately, in which case the comment has already been addressed. Please see CLH's response to comment 5 above.

c. As stated before, this section does not address fishing advisories.

This comment has already been addressed. Please see CLH's responses to comments 7 and 8 above.

- d. The quantities of fish and crabs ingestion in the entire diet may be more representative of consumption patterns and should not be ignored.*

CLH disagrees with this comment. The rate of consumption of self-caught fish and crabs from the Study Area is the relevant parameter for this study and the subsequent risk assessment for the Study Area. This is most directly and easily obtained by asking about the disposition of fish and crab caught on the fishing/crabbing outing (the exposure event). General consumption from unknown sources cannot be tied to such exposure events. Moreover, the sorting out of the amount of consumption from different sources, such as asking the fraction of general consumption derived from the Study Area, requires asking questions that are difficult for respondents to answer accurately.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- e. The time frame should include current and future exposures consistent with RAGS and other Superfund guidance documents.*

This comment has already been addressed. Please see CLH's responses to comments 22.d and 26.a above.

30. Page 2-4

- a. What demographic information is available for the population of interest?*

United States census data are available. However, the census data concern those who live in the vicinity, and the full set of demographic characteristics of those using the Study Area is not known.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- b. How will the survey address the specific needs of this group?*

CLH does not understand this comment. The use of a properly designed and pre-tested on-site intercept approach results in surveys that are specifically tailored to the user population.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- c. What criteria will be used to determine that a sufficiently high proportion of the potential exposed individuals are contacted?*

This comment has already been addressed. Please see CLH's response to comment 6.b above. For further clarification on this issue, the amount of survey effort in the

Draft CASWP was compared to other intercept creel/angler surveys, and the sampling simulation demonstrated a low probability of missing subsistence/high frequency anglers.

31. Page 2-5

There appears to be an inconsistency between statements that data is being collected to meet HHRA requirements and that the HHRA requirements cannot be developed?

CLH does not believe that there is any such inconsistency. The data are being collected to meet the needs of a HHRA to be performed in accordance with EPA guidance. However, development of the specific HHRA protocol requires the CAS study results to define exposure scenarios and specific statistical and other procedures, as these may depend on the numbers of respondents and the nature of the data.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

32. Page 2-6

a. What literature reviews are planned?

In response to this comment, following is a summary of the literature review that has been conducted to date and is included in the revised CASWP. No additional literature reviews are planned for the revised CASWP.

Prior to developing and submitting the Draft ESP in December 1995, CLH's representatives reviewed the one study that had been conducted and published at that time by Dr. Burger and her colleagues at Rutgers University. The study, entitled *Fishing in contaminated waters: knowledge and risk perception of hazards by fishermen in New York City*, published by Burger, J., K. Staine, and M. Gochfeld in the *Journal of Toxicology and Environmental Health* (39:95-105) in 1993, reported on the perception that people fishing in Jamaica Bay, New York, had concerning water pollution and fishing-related health advisories in that waterway. CLH concluded at that time that the results of the study had little relevance to the design or conduct of a CAS for the Passaic River Study Area, because the objectives and methodologies, and the waterways and angler populations, of Dr. Burger's study were entirely different than those being proposed in the Study Area CAS.

Following receipt of EPA's comments on the Draft ESP, CLH's representatives contacted Dr. Kerry Kirk Pflugh, who at that time was also employed by Rutgers University (now with NJDEP). Dr. Kirk Pflugh, along with her colleagues, including Dr. Burger, was at that time analyzing the results of a survey they had conducted of urban anglers from 26 sites in the "Newark Bay Complex." While the objectives of Dr. Kirk Pflugh's work were similar to those of Dr. Burger's in Jamaica Bay (i.e., angler perception of fishing-related health advisories), her surveys were conducted in areas immediately surrounding (but not within) the Passaic River Study Area. For

that reason, CLH's representatives discussed the population demographics and methodological logistics of Dr. Kirk Pflugh's survey with her, and the insights gained from this discussion with Dr. Kirk Pflugh were used in the design of the Draft CASWP. CLH's representatives requested that Dr. Kirk Pflugh provide reports or data from her survey, in order that they could be considered and referenced in the design of the CAS. No reports or data were provided by Dr. Kirk Pflugh.

Since the time of the Draft ESP submittal, three additional relevant papers have been published, including two papers published in 1999 after the development of the Draft CASWP, that summarize the results of the aforementioned study by Dr. Kirk Pflugh, and one paper that summarizes another study conducted by Dr. Burger and one of her graduate students. The titles of these papers are:

May, H. and J. Burger. 1996. Fishing in a polluted estuary: fishing behavior, fish consumption, and potential risk. Risk Analysis 16(4):459-471.

Burger, J., K. Kirk Pflugh, L. Lurig, L.A. Von Hagen, and S. Von Hagen. 1999. Fishing in urban New Jersey: ethnicity affects information sources, perception, and compliance. Risk Analysis 19(2):217-229.

Kirk Pflugh, K., L. Lurig, L.A. Von Hagen, S. Von Hagen, and J. Burger. 1999. Urban anglers' perception of risk from contaminated fish. The Science of the Total Environment 228:203-218.

The May and Burger (1996) study was based on interviews of people who fish and crab in Arthur Kill, Raritan Bay, and at the New Jersey shore. Again, this study dealt with the issue of anglers' perceptions of pollution and fishing/crabbing-related health advisories. Similar to Dr. Burger's Jamaica Bay study, the objectives and waterways of this more recent study were different than those for the Passaic River Study Area CAS. Therefore, this study was not considered relevant to the development or implementation of the CAS and, therefore, was not discussed in the Draft CASWP.

The Kirk Pflugh et al. (1999) and Burger et al. (1999) papers are reviewed as appropriate in the revised CASWP. Written summaries explaining how each of the aforementioned studies/publications were considered in the design of the CAS are included in the revised CASWP.

b. How will the specific language requirements be addressed in the analyses?

This comment has already been addressed. Please see CLH's response to comment 30.a above.

33. Page 2-7

- a. *What is the schedule for pre-testing that is being planned?*
- b. *What is the protocol for pre-testing in English and other languages?*
- c. *How many people will participate in this evaluation?*

The general activities are to include focus group, one-on-one, and field pre-testing. These will take place in English, Spanish, and/or Portuguese. Approximately 30-50 people will participate in the survey pre-test, currently scheduled to be conducted within a 4-week period.

In response to this comment, additional detail regarding the pre-test has been provided in the revised CASWP.

34. Page 2-8

- a. *What is meant by “linguistically-isolated respondent?”*

In this CAS, a “linguistically-isolated respondent” is a respondent who does not speak English, Spanish, or Portuguese.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- b. *What does “real-time translation” mean?*

A “real time translation” is one that takes place during and at the same pace as the interview (i.e., live simultaneous translations inserted between the interviewer and respondent).

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- c. *What translation process will be used?*

This comment has already been addressed. Please see CLH’s response to comment 18.b above.

- d. *What is the basis for the selected languages listed?*

The bases were state census data, and the results published in Kirk Pflugh et al. (1999) and Burger et al. (1999).

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- e. *What dialects will be included in the translations?*

No specific dialects were identified by Kirk Pflugh et al. (1999) or Burger et al. (1999). Therefore, none are built into the revised CASWP.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

35. Page 2-9

a. *Where is the summary of literature identified in the document?*

This comment has already been addressed. Please see CLH's response to comment 32.a above.

b. *We disagree with the statement regarding the identification of the consumers of fish within the Study Area. Can't outreach processes within the community be used to identify the populations of concern?*

The best chance of contacting individuals who fish is to use an intercept survey, as recommended by EPA guidance (1998; 1992), and as planned here. It should be noted that Kirk Pflugh et al. (1999) and Burger et al. (1999) did not find interactions with community groups helpful for identifying anglers. Thus, it does not appear that such an "outreach process" will be useful for the Study Area.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

36. Page 2-10

a. *What is the scientific basis for the study-area angler approach being used?*

The scientific basis for roving creel surveys is derived from Robson (1960; 1961) and discussed in detail by Malvestuto (1996). More importantly however, EPA guidance (1998; 1992) clearly supports the selection of an on-site intercept survey for single water bodies where subsistence anglers may be present. In addition, the general scientific literature on conducting sample surveys supports the specified approach.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. *How will the issues of "small n" be addressed and used in the survey?*

This comment has already been addressed. Please see CLH's response to comment 19 above.

c. *How is the term "vicinity of the SA" being defined?*

This comment refers to the household survey. As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

d. The analysis of the literature should be provided for the creel and angler surveys.

This comment has already been addressed. Please see CLH's response to comment 32.a above.

37. Page 2-11

a. A description of the analyses for the "prediction error" should be provided in the document.

This comment refers to the household survey. As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

b. The translation procedures should be defined and discussed.

This comment has already been addressed. Please see CLH's response to comment 18.b above.

c. How will "drift" in survey technique be addressed?

None of CLH's contractors, including survey experts, knows what "drift" in survey technique means, and to our knowledge it is not a term used in standard survey protocols or guidance.

Assuming "drift" relates to survey continuity, continuity will be maintained between survey teams in terms of the approach to the interviews and interview techniques through careful training and supervision.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

d. What training will the surveyors receive in the questionnaire, etc.?

This issue was already addressed in the Draft CASWP. However, for completeness, this issue is discussed below.

For the on-site survey, field staff required for this effort will require a unique skill set. Interviewers need to possess interviewing skills as well as knowledge of species of fish and crabs. Also, they will have to account for linguistic isolation as a potential barrier. To meet this set of skills, survey professionals will train appropriate field staff to conduct in-person interviews.

Training will consist of:

- an overview of project-specific goals
- interviewing techniques
- survey conduct
- the need for sensitivity to the survey population
- review of the survey instruments
- practice using the survey instruments
- techniques for gaining cooperation, particularly in suspicious populations and in non-English speaking populations
- fish/crab species identification
- use of AT&T translation services for conducting telephone interviews of linguistically isolated fishermen.

e. How will the collected data be transferred to the computer tapes?

Data from survey forms will be double key entered and then compared for verification. Any differences in the data files will be resolved by checking the original survey forms. This is standard procedure for surveys of this type.

We will not be using computer tapes; rather data will be stored on hard disks and similar media as appropriate.

These clarifications were made in the revised CASWP.

f. The QA/QC procedures should be more clearly defined.

In response to this comment, the QA/QC procedures have been more clearly defined in the revised CASWP. The points of clarification include composition of survey team, supervision procedures, and data handling and verification.

g. Details regarding the database structure and EPA's access to the results of the survey should be provided.

This comment has already been addressed. Please see CLH's response to comment 27.h above.

38. Page 2-12

A more detailed discussion of the data response analysis should be provided.

Data analysis for the CAS consists of descriptive statistics (e.g., means, standard deviations, skewness, maxima and minima) for each question response. In response to this comment, this has been further clarified in the revised CASWP.

39. Page 3-1

What expert opinion was used? How were the experts selected? What questions were addressed by the experts?

Expert opinion was used to inform development of the CASWP. CLH chose its project team based on expertise in the fields of human health risk assessment and survey design and implementation. Resumes can be provided upon request. Survey design and implementation, and data use objectives of the CAS in terms of risk assessment needs were discussed with these experts.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

40. Page 3-2

a. How will the interviews assure that the individuals in the survey represent the general population?

This comment has already been addressed. Please see CLH's response to comment 19 above. For further clarification, the individuals in the survey are meant to represent those who use the Study Area.

b. What is meant by a small number? What n is too small to make the survey results meaningful for this type of analyses.

This comment has already been addressed. Please see CLH's response to comment 19 above.

c. Where are the details of the Monte Carlo Analysis? What model was used? How was the model developed, what assumptions and distributions were used and what was the basis for these data? A statistician should review this assessment when submitted to the EPA.

The full details are contained in Appendix B of the Draft CASWP, including all the assumptions and distributions used. The algorithm is stated in Appendix B; the model was programmed in Fortran.

The basis of the data is general experience with angler surveys; the data are not based on any particular empirical database. The model was developed with the assistance of a professional statistician.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

d. In bullet #2, what data in the area was used to support this conclusion?

The data used are discussed in Appendix B of the Draft CASWP. General qualitative features of the Study Area were incorporated into the simulation.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

e. In bullet #3, this statement is unclear and should be further evaluated.

In response to this comment, the statement has been clarified in the revised CASWP.

41. Figure 1-2

What is the basis for this target area selection?

There are no target areas on Figure 1-2. Three survey targets are identified as are five survey access locations. However, in response to other EPA comments, the general sampling approach has been modified and no longer uses these target or access points to structure the sampling locations.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

42. Page 3-3

a. Wouldn't there be a preferential sampling period of early morning and late evening for subsistence anglers? A pre-survey of the population would be helpful.

This comment has already been addressed. Please see CLH's responses to comments 6.b and 40.e above.

b. The Up stream and Down Stream analysis should be better defined.

In response to other EPA comments, the sampling approach has been modified and the distinction between upstream and downstream analysis has been eliminated.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

43. Page 3-4

a. What will be the criteria for selecting individuals when more than 2 people are identified fishing in a specific area? Why was 2 selected?

This will be done by systematic sampling (i.e., by noting the individuals present from upriver to down river along the river bank and choosing 2 by a random selection method). The number "2" was selected based on the desire to complete a minimum of one survey cycle through the Study Area for each survey day.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. What are the definitions for ethnicity that are being used?

This comment has already been addressed. Please see CLH's response to comment 26.c above.

c. Why is a broad age category being used and what is the range of this category?

This is an enumeration form filled out based on observations, so that some information is obtained about users even if there is a refusal or too many individuals exist to interview all of them at one time. Narrow categories are subject to error from observation alone. Three categories are used: children (less than 18 years of age), adults (to age 60) and seniors (greater than age 60).

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

d. Where do the Portuguese fall within the race/ethnicity identification?

Portuguese will constitute an ethnic category in the on-site survey; for enumeration purposes it will be difficult to distinguish visually between Hispanic and Portuguese anglers and this will be combined into one category.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

e. Will a minimum number in each category be identified?

No.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

f. Are the ethnicity identifications being self identified?

These are identified visually by the enumerator; training will be used to assist this process. In the interview proper, self-report will be used.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

g. Will those not selected be interviewed?

The statement refers to selection for an interview. Except when there are more than two individuals at one location, all individuals will be selected for interview. Those not selected at one location will be interviewed on the next pass through that location if they are still there.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

44. Page 3-5

What is the maximum number of responders?

As identified in the Draft CASWP, the maximum number has been set at 1,000.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

45. Page 3-6

The places suggested in this "roving intercept" should be identified.

These are identified in Figure 1-2 and on page 3-19 of the Draft CASWP. In response to this comment, the use of these locations is clarified in the revised CASWP.

46. Page 3-7

Need to have this reviewed by a statistician.

The sampling plan was developed with the assistance of a professional statistician.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

47. Page 3-13

a. *Where are the results of the interviews with the bait and tackle shop store owner? The boat yard operation? How were these selected?*

These were selected by convenience sampling; they are the only known such places near the Study Area. The results are discussed in the text of the Draft CASWP on page 3-14 and include: (1) that more fishing occurs on weekends, (2) that more fishing occurs during the spring, summer and fall period; (3) a general concurrence with the seasonality identified by fish biologists on fishing and crabbing activity, and (4) there is generally little fishing activity in the Study Area.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- b. *Why was the Three Rivers Study selected for comparison? What other studies were evaluated but not included? How similar are these rivers and fish species?*

This study was selected because of the information on winter angling and day/weekend angling and the urban nature of the study area. No other surveys were considered in the text of the Draft CASWP. The fish species are different in that Three Rivers is a freshwater system and the Study Area is estuarine. However, this does not affect the appropriateness of using the Three Rivers survey in the CAS simulation.

In response to this comment, the revised CASWP includes a more rigorous review of other surveys in the geographic area surrounding the Study Area, as discussed in CLH's response to comment 32.a above.

48. *Page 3-14*

Is the pattern identified in #4 consistent with a subsistence population?

The pattern is potentially consistent with subsistence anglers. The qualitative research did not restrict attention to recreational anglers.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

49. *Page 3-16*

A summary of the data should be provided.

CLH does not understand this comment, because what appears in the Draft CASWP is a summary of the data.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

50. *Page 3-17*

The discussion in section 3.2.2.4 does not refer to weather, but rather accessibility.

This discussion does indeed refer to weather. The weather affects the sampling by boat, which refers to the sites only accessible by boat.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

51. *Page 3-18*

a. *Were anglers found in this area?*

Anglers have been seen in the Study Area at various times by CLH's representatives during site visits and field sampling programs related to the Ecological Sampling Plan.

In response to this comment, a summary of these observations has been provided in the revised CASWP.

b. How will hot spot areas be addressed? Will these areas be oversampled?

CLH does not fully understand this question. By "hot spot" we assume the Agency means specific locations that have a relatively high angler usage. Such areas will be well sampled in the CAS, but not oversampled. This would violate the randomized study design of the CAS and limit use of the data to support an accurate risk assessment.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

52. Page 3-21

How will the data on the resampled person be included in the analysis? Will this person be counted twice?

Questions are included in the survey to identify those who have been sampled previously during the day and over the course of the survey. People will be counted more than once and re-interviewed in accordance with the sampling protocol. How the data for the re-sampled person will be treated in the analysis awaits final HHRA protocols.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

53. Page 4-1

- a. What are the minimum and maximum number of people to be included in the random-digit telephone survey.*
- b. The statement regarding the qualitative assessment should be further characterized i.e., what is the expected use of this information in the risk assessment?*
- c. How will individuals with cellular phones and no phone number be assessed in this analysis?*
- d. No information is provided regarding how non-responders will be evaluated?*
- e. Why aren't questions regarding the amount of fishing or crabbing an individual may participate in the absence of a fishing advisory/ban included in the document?*

These comments refer to the household survey. As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

54. Page 4-4

- a. *What is the length of the survey anticipated?*
- b. *What is the absolute minimum sample size?*
- c. *Based on the criteria of adult participation, how will risks and activity patterns of children, especially teenagers be ascertained and assessed in the document?*

These comments refer to the household survey. As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

55. Page 5-1

Further details on the weighting of the sample to adjust sample characteristics to the population characteristics should be provided.

This comment refers to the household survey. As discussed in CLH's responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

Appendices

Appendix A

56. General

The on-site survey does not ask about fish or crab eaten from the area that are not self caught (caught by friends, given to them, restaurants, etc.)

In the CAS, we are not interested in all sources of fish and crabs consumed in general, but rather the risks posed by consuming fish and crabs caught by the respondent in the Study Area. Whether gift or restaurant fish or crabs originated from the Study Area cannot be definitively determined by the survey respondent. Hence, no questions about other than self-caught fish and crabs are included in the survey.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

57. Page A-1

What age ranges are being identified for the census anglers?

Children, up to age 18, adults age 19 to 60, and seniors over age 60.

- a. *There is a potential misclassification bias in the determining of anglers that should be addressed in the discussion.*
- b. *What age ranges are being identified for the census anglers?*

CLH agrees that this potential exists, but it is unavoidable. Broad categories were specified to limit misclassification to the extent practicable. The data will be used only to get some idea of these variables for non-respondents or those not selected for interview.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

- b. How would the interviewer determine the ethnic origin of an angler by observation only? (Black, white, male or female is obvious, but Hispanic may not be so obvious)*

Carefully training the interviewers will assist in recognition of ethnicity, but some unavoidable potential for misclassification will still exist.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

58. Page A-5

- a. Are the fish to be eaten going to be weighed before or after gutting?*
- b. How will this be addressed for those who have gutted the fish in anticipation of leaving for home?*

The fish are not going to be weighed, instead their length will be measured.

In response to this comment, the survey form has been modified in the revised CASWP to provide for the surveyor to note whether or not the fish has been gutted.

59. Page A-6

- a. Will fish species information be obtained?*
- b. Fish soup may also be a route of exposure that is not included in the fish cooking practices?*
- c. Why aren't questions regarding use of pan drippings included in the assessment?*

Fish species information will be obtained from the survey.

In response to this comment, fish soup and the use of pan drippings have been added to the list of cooking possibilities in the revised CASWP.

60. Page A-7

- a. It doesn't appear that information regarding the number of fish meals per year is being collected during the survey? This should be clarified.*

Annual exposure from eating fish can be calculated from the survey based on annual number of trips and the exposure per trip. A direct question about annual meals requires re-call over a long period and was judged to be an unreliable approach. The

specified approach will use more data and, therefore, will be more accurate than a long period re-call.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. Question 30; what is the rationale for asking for fraction of the fish eaten instead of portion size?

Both a fractional and a portion size approach will be used, where the latter is a comparison of the meal size to two portion sizes. This is suggested because there is no good basis for using one approach *versus* the other. Pre-testing may reveal that one approach is preferred. It is expected that the fraction of fish eaten will provide more accurate data given the variation of fish and crab sizes that are expected to be observed.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

61. Page A-9

a. Why is data only collected for the past five years?

Recall beyond a 5 year period was judged to be unreliable. The year when the person first fished is being asked, as well as whether the respondent fished every year since then.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. Why are no questions regarding the fish advisories/bans included in the questions?

This comment has already been addressed. Please see CLH's response to comment 8 above.

Appendix B

62. General

a. The basis of the parameters are not specifically stated. Is this site-specific data that is being used, and if not, how similar is this river to the national surveys on which this was based?

The data being used are not site-specific. The data are not based on any particular site or national survey results. The data are based on the experience of CLH's experts regarding fishing and fishing behavior, and were chosen to be "representative" of the types of variability that will be faced in a creel and angler survey.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

b. Why are only 30 simulations presented in the analyses?

Many simulations are needed when the underlying functional relationship to be simulated is highly non-linear. Since 5,000 repetitions are used for each draw of a hypothetical “true” visitation pattern to uncover the distribution of the selected non-linear statistics, all that is needed from variations in the underlying “truth” is to ensure that conclusions are not based on a single truth. CLH’s experts believe that 30 simulations is a sufficient number to cover variability in the underlying truth for the purposes of this analysis.

Per the explanation provided, there are no modifications to the Draft CASWP required to address this comment.

Appendix C

63. General

- a. What is the length of this survey?*
- b. Are there more local terms for the study area that may be more appropriate to use in this survey?*
- c. The telephone survey focuses on fishing habits and not eating habits.*
- d. Consumption estimates cannot be accurately determined if the questionnaire does not ask about how much they eat from the study area.*

This comment refers to the household survey. As discussed in CLH’s responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

64. Page C-8

Why isn’t information on Portuguese included in addition to Spanish or Hispanic?

This comment refers to the household survey. As discussed in CLH’s responses to comments 4.b through 4.e above, the household survey has been removed from the revised CASWP.

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